

REMARKS

Claims 1-26 are pending in the application.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show a current sink, as claimed in Claims 7 and 8 as described in the specification.

Claim 9 is objected to because of the following informalities: in line 4, it is unclear to the Examiner what exactly "its" refers to in the claim. Appropriate correction is required.

Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 4-17 and 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Alt (6,829,503 B2).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 1 above, and further in view of Takehara et al (2002/0022787 A1)(Takehara) in view of Duong et al (6,740,518 B1)(Duong).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 1 above, and further in view of Baura et al (6,561,986 B2)(Baura).

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 12 above, and further in view of Carter et al (5,674,264)(Carter).

Claim Objections

The Examiner objected to **Claim 9**, stating "it is unclear...what 'its' refers to in [line 4 of] the claim", which recites "the presence of other than the nominal quantity of fluid changes the anatomical space from *its* nominal shape", (Office Action, Page 2, § 1). Applicants refer the Examiner to the immediately preceding portion of the claim which recites, "the injection and measurement vectors define *a nominal shape of the anatomical space* in the presence of a nominal quantity of fluid", (emphasis provided). This recited limitation(s) establish a clear interpretational basis that it is *the anatomical space* which has a nominal shape. No other 'anatomical space' or 'nominal shape' is recited in the preceding claims or elsewhere in Claim 9. Further, the recited limitation(s) associates the nominal shape of the anatomical space with a "nominal quantity of fluid".

Thus, applicants respectfully submit that when the claim subsequently recites "the presence of *other than* the nominal quantity of fluid changes *the anatomical space from its nominal shape*", it is sufficiently clear that it is the nominal shape of *the same anatomical space* as recited above (indicated as antecedent, "*the anatomical space*") that is changed by the

presence of *other than* the nominal quantity of fluid. Therefore, applicants submit it is just as clear that “its” (i.e., “its nominal shape”) refers to the shape of *the anatomical space*, and would be so recognized by one having ordinary skill in the art. Applicants respectfully submit that a clear interpretational basis is established in the intrinsic content and context of the claim itself, and that the word “its”, as used in context, is not ambiguous, vague, or misleading, but rather ‘particularly points out and distinctly claims the subject matter which the applicant regards as his invention’.

For at least this reason, applicants submit that the objection to claim 9 is improper, that no correction is required to overcome the objection, and respectfully request withdrawal of the objection.

Claim Rejections – 35 U.S.C. § 112

Claims 7 and 8 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, Examiner asserts “[t]he current specification does not support the claimed ‘a current source and a current sink’ in Claim 7, and ‘multiple current sources and multiple current sinks’ as recited in Claim 8. However, applicants respectfully submit that this assertion is incorrect, as would be understood by one having skill in the art.

The plain meaning of a ‘current source’ is a “point *from which* conventional current flows (electrons flow toward it)”. Conversely, a ‘current sink’ is a “point *toward which* conventional current flows (electrons flow away from it)”, (Modern Dictionary of Electronics, Seventh Edition; page 166, Rudolf F. Graf, 1999)(emphasis provided). One of ordinary skill in the art will also recognize that a closed circuit must be formed in order for current to flow. Thus, when electricity flows through a functioning electrical circuit, with a mammalian body interposed between two contacts and forming a part of the circuit, one having ordinary skill in the art will recognize that one of the contacts acts as a current source (e.g., a point from which current flows into the body), and the other contact acts as a current sink (e.g., a point toward which current flows from the body).

One having ordinary skill in the art would also readily recognize that by simply reversing the direction of current flow in a circuit, a contact which previously acted as (and therefore is defined as) a current source instead becomes a current sink, and vice versa. The plain meaning in the electronic arts of ‘current source’ and ‘current sink’ includes the ability for a single contact to function as either with respect to another contact in a circuit. This

relationship is so fundamental that, in light of the overall description provided by the applicant, it does not require elaborate description to those having skill in the art.

Additionally, one having ordinary skill in the art will recognize that current (measured in 'amperes') and electrical potential (measured in 'volts') are concurrent characteristics of electricity in an operating circuit, each of which can be detected, measured, and quantified. Thus, an electrical contact (e.g., electrode) toward and through which an electrical current flows, can concurrently be both a current sink and a voltage sensing element. This understanding is also so fundamental that, in light of the overall description provided by applicants, elaborate details are not required to clearly convey full understanding of the described embodiments to those having skill in the art.

Claim 1, from which claims 7 and 8 depend, clearly recites,

... providing a first set of injection electrodes ... positioning *members* of the first set of electrodes on the body to introduce electrical current flow through the mammalian tissue and thereby establish flow paths that define injection vectors along which *electrical currents flow between two or more injection electrodes*, (Emphasis provided)

This principle is also reflected in applicants' specification. For example, "Electrical current flow paths established by the injection electrodes define injection vectors generally along which *electrical currents flow between two or more of the injection electrodes*", (para. [0012])(emphasis provided). One having ordinary skill in the art would understand that if current is flowing 'between two ... injection electrodes' in a circuit, that the current is flowing from one of the electrodes (i.e., current source) and is flowing toward the other electrode (i.e., current sink). This description is entirely consistent with, and provides intrinsic support for Claim 7, which recites,

... each member of the first set includes a current source and a current sink, the current source and current sink being positioned at locations on the body such that electrical current *flowing from* a current source of one of the members *flows into* a current sink of another one of the members[.]

The first set of injection electrodes includes at least two members, with current flowing from a current source on one member to a current sink on another member. As applicant describes at paragraph [0053], and the Office Action concedes, each of a plurality of contacts comprising members of a 'first set of injection electrodes' can be one of a current source, a current sink, or a voltage sensing element.

The more generalized, plain meaning of 'current source' and 'current sink' described above does not conflict with applicants' more specific use of the term "injection current source". Applicants use "injection current source" as a reference label for a component of the

invented system, according to an embodiment. For example, “injection *current source* 30, which generates the electrical current to be injected through the injection electrodes”, (para. [0037])(emphasis provided), which clearly distinguishes the ‘injection current source 30’ from the injection electrodes (which includes at least one current source electrode and one current sink electrode). This is a specialized use of ‘current source’, and does not alter the more general plain meaning as it would be applied and understood by one having ordinary skill in the art with reference to the injection electrodes.

Applicants therefore respectfully submit that the specification and claims, as originally presented, provide adequate written description for “‘a current source and a current sink’ in Claim 7, and ‘multiple current sources and multiple current sinks’ in Claim 8, as would be understood by one having skill in the relevant art.

For at least these reasons, applicants respectfully submit the rejections of Claims 7 and 8 under 35 U.S.C. §112, first paragraph, are improper, and request withdrawal of the rejections from both claims.

Drawing Objections – 35 U.S.C. § 183

The drawings are objected to under 37 CFR 1.83(a) because the Examiner asserts they fail to show a current sink, as claimed in Claims 7 and 8 as described in the specification. However, this assertion is incorrect, and the discussion above indicates.

As one example, paragraph [0029] states,

An electrode ‘patch’ may contain at least two electrically active elements or electrodes, one of which injects electrical current and the other one or other ones of which measure the resulting voltage, in association with other current injection and voltage measurement electrodes.

Paragraph [0030] further describes that,

FIGS. 1A and 1B are respective top and bottom views of an exemplary multiple electrode assembly 10 formed on a patch that can be applied on the skin of a patient . . . FIG. 1B shows active electrode conductive contact areas 12c, 14c, and 16c of electrodes 12, 14, and 16, respectively. One or more of electrodes 12, 14, and 16 can be used for electrical current injection or voltage sensing. For example, electrical current could be injected through circular electrode 12 and voltage measurements taken from one or both of segment electrodes 14 and 16.

As discussed above with regard to the asserted 35 U.S.C. §112, first paragraph rejections, one having ordinary skill in the art will readily recognize from applicants description that FIG. 1B depicts at least one electrode configured to function as a current source (from which current flows into human body tissues), and at least another electrode

configured to function as a current sink (to which current flows after passing through the human body tissues).

FIGS. 3 also depicts "locations of electrode placement" (para. [0043]), and "the location of the current injection and measurement vectors used to acquire the bio-impedance data representative of the regions defined by the vectors of the anatomical space", (para. [0044]), "along which electrical currents flow *between two or more injection electrodes*", (Claim 1)(emphasis provided). Thus, FIG. 3 also depicts at least one current source and at least one current sink.

Applicants respectfully submit that the drawing figures, as originally presented, depict at least one 'current sink', as would be readily understood by one having skill in the art. For at least the reasons provided above, applicants respectfully submit the objection to the drawing figures under 37 C.F.R. §1.83(a) is improper, that no amendments to the drawings are necessary to overcome the objection, and therefore request withdrawal of the objection.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 4-17 and 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Alt. The Office Action asserts that Alt discloses applicants' recited limitations of independent claim 1, including "positioning members of the first set of electrodes on the body", and "positioning members of the second set of electrodes on the body", as well as independent claim 12 including, "multiple electrodes configured for . . . placement on the body".

However, applicants respectfully submit that Alt fails to so disclose, for at least the reason that Alt exclusively describes implanting electrodes *within a body* (expressly requiring surgical entry into the body), not *on a body*. "It is implanted in a 'subcutaneous pocket formed by the surgeon in the patient's chest", (Col. 1, lines 42-44)(see also FIG 2). "[T]he device is prevented from turning within its subcutaneous pocket which would otherwise position the surface electrodes at the *wrong side-namely, toward the exterior of the patient's body*", (Col. 2, lines 64-Col. 3, line 1)(emphasis provided). "[A]n impedance signal is developed which represents the impedance of the lungs and heart tissue by virtue of current injected into the circuit path that establishes a field through that portion of the body from device 18", (Col. 3, lines 13-17).

From the above passages, it will be clear to one having ordinary skill in the art that the exterior of the patient's body is intentionally excluded from the intended circuit path of Alt; i.e., is not interposed between the electrodes and the lung and heart tissue.

This is entirely unlike applicants' invented embodiments configured for positioning electrodes *on a body*. As consistently described throughout the specification, depicted in the figures, and as would be understood by one having ordinary skill in the art, "on the body" in applicants' claims refers to an exterior surface of a body. "The method entails positioning members of a set of injection electrodes and members of a set of measurement electrodes at known locations *on the surface of the body of a mammal*", (para. [0012])(emphasis provided). "[E]lectrodes are made of electrically conductive material, preferably Ag--AgCl with an electrically conductive gel to couple *to the body surface*", (para. [0028])(emphasis provided). "The substrate or 'backing' of the electrode patch has an adhesive to secure it *to the body surface*", (para. [0029])(emphasis provided). "The vectors are designated as current paths or measurement paths between pairs of electrodes placed *on the body surface*", (para. [0031])(emphasis provided). "FIG. 7 shows examples of additional locations for placement of current injection and measurement electrodes *on mammalian body 70*", (para. [0050])(emphasis provided).

Applicant recognizes that "[d]uring patent examination, the pending claims must be 'given their broadest *reasonable interpretation consistent with the specification*'", (MPEP 2111)(emphasis provided). As stated, such interpretation is not unbounded. It must be 'reasonable', and must be made "in light of the specification as it would be interpreted by one of ordinary skill in the art." (*In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 [70 USPQ2d 1827] (Fed. Cir. 2004); MPEP 2111). However, interpreting applicants' recited "positioning . . . electrodes *on the body*" to be anticipated by Alt's positioning electrodes *wholly within a body* steps beyond the boundaries of reasonableness, and one having ordinary skill in the art would not arrive at such interpretation in light of applicants' specification.

Additionally, the plain meaning of 'on the body' does not encompass a device implanted within the body. "On: 1.-Used to indicate: a. Position above and in contact with, b. Contact with a surface, regardless of position", (Webster's II New Riverside University Dictionary, page 820, 1988). One having ordinary skill in the art, when using the word 'on' to indicate a device located within a human body, will generally refer to the device as being on some internal structure, or being *implanted* on a particular side or other specific location, not 'on the body' generally. For example, Alt describes in claim 13, "device *implanted on* the lower left side of the thoracic [rib] cage", (see also Col. 3, lines 10-12, indicating *implantation* 'on' the left anterior thorax)(emphasis provided). Inasmuch as claim 13 depends from and includes the limitations of independent claim 1, which recites, "the device implanted subcutaneously *in the patient's body*" (emphasis provided), Alt's use of the word

“on” clearly and intentionally refers to being on an internal structure, and does not disclose applicant’s recited “on the body”.

For at least these reasons, applicants respectfully submit that the Non-Final Office Action fails to establish a *prima facie* basis for the asserted 35 U.S.C. §102(e) rejections of independent claims 1 and 12 over Alt, and request withdrawal of the rejections therefrom. Likewise, inasmuch as claims 4-11, as well as claims 17 and 22-26, include at least the distinct limitations of independent claims 1 and 12, respectively, from which they depend either directly or indirectly, applicants likewise request withdrawal of the 35 U.S.C. §102(e) rejections of claims 4-11, and from claims 17 and 22-26.

To provide additional clarity, although applicants do not believe it necessary to traverse the rejections (as detailed above), applicants hereby amend claims 1 and 12 to even more definitely and distinctly claim their invention. Specifically, applicants amend claims 1 and 12 to include the clarifying phrase “*an external surface of*”, e.g., “on an external surface of the body”. Applicants contend this phrase neither increases nor decreases the scope of the claims so amended, as discussed above and as would be understood by one having skill in the art. However, applicants recognize the Office’s desire for clarity, and seek to advance the efficient prosecution of the application.

Claim Rejections – 35 U.S.C. § 103

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 1 above, and further in view of Takehara in view of Duong. The Office Action concedes that the combined references of “Alt and Takehara et al however fail to disclose analyzing the acquired data through the use of Fourier transform and data reduction”, (Page 8, § 8), but asserts that Duong teaches the limitation(s) not provided by Alt as modified by Takehara.

However, applicants respectfully submit that the assertion constitutes factual error for at least the reason that the asserted modification fails to disclose one or more limitations recited in applicants’ claim 2. Applicants previously explained this failure in applicants’ 5 March 2008 submission, a response to which the Office *has not yet been provided*.

Specifically, the Office Action cites Column 89, lines 1-21 as support for Duong disclosing analyzing acquired data through the use of data reduction. One having ordinary skill in the art will recognize the error of the assertion.

According to the cited section of Duong:

"Curve fitting and peak recognition can be achieved by modeling the data . . . using linear models such as the Least squares method . . . and Chisquare fitting (Bevington et al., *Data Reduction and Error Analysis for the Physical Sciences*, N.Y. McGraw Hill (1969) . . .) or nonlinear models such as Levenberg-Marquardt . . . and other nonlinear least-squares . . . methods. (Col. 89, lines 1-21)

Thus, the Office Action appears to suggest that because the words "Data Reduction" appear in the title of a publication cited in the reference, that the reference teaches the limitation of 'data reduction'. One having ordinary skill in the art would recognize that the asserted reasoning is without basis.

The publication cited in the reference is titled Data Reduction and Error Analysis for the Physical Sciences (emphasis provided), identifying two distinct topics; Data Reduction, and Error Analysis. However, what the reference expressly describes are the least squares method, Chisquare fitting method, and Levenberg-Marquardt method. In particular, those having skill in the art will recognize all of these as methods for 'curve fitting', and are used for *error analysis*, not data reduction. Therefore, it relates only to the second topic of the publication, 'Error Analysis'.

Quite simply, Duong says absolutely nothing about data reduction, and does not rely upon or employ the publication for any purpose related to *data reduction*. 'The phrase 'Data Reduction' simply happens to be in the title of a resource cited for an entirely separate purpose, and the extensive 110-column disclosure of Duong completely fails to disclose applicants' recited limitation wherein "the analyzing of the electrical bio-impedance values includes Fourier analysis *and data reduction*", (Emphasis provided). Therefore, Duong fails to correct the failures of Alt as modified by Takehara.

For at least these reasons, as well as the reasons discussed above regarding the asserted 35 U.S.C. §102(e) rejection over Alt alone, applicants respectfully submit that the combined references fail to disclose at least the limitations of applicants' claim 2. Therefore, applicants respectfully submit that claim 2 is allowable over the references, either alone or when combined, and request withdrawal of the 35 U.S.C. § 103(a) rejection from claim 2.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 1 above, and further in view of Baura. The Office Action asserts that "it would have been obvious to modify the means of Alt to include waveform analysis of the acquired signals, as per the teachings of Baura et al", (Office Action, Page 9, § 9).

However, so modified, Alt remains an implantable device having electrodes entirely within, not *on* a body, nor in particular, on an *external surface* of the body. As discussed

above regarding the asserted 35 U.S.C. §102(e) rejection, Alt fails to disclose at least the limitations in applicants' independent claim 1, from which Claim 3 depends, and the distinct limitations of which Claim 3 includes, (e.g., at least "positioning members of the first set of electrodes on the body", and "positioning members of the second set of electrodes on the body").

For at least these reasons, as well as the reasons discussed above regarding the asserted 35 U.S.C. §102(e) rejection over Alt alone, applicants respectfully submit that the combined references fail to disclose at least the limitations of applicants' claim 3. Therefore, applicants respectfully submit that claim 3 is allowable over the references, either alone or when combined, and request withdrawal of the 35 U.S.C. § 103(a) rejection from claim 3.

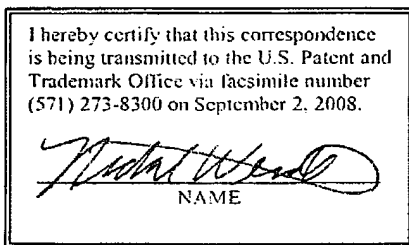
Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 12 above, and further in view of Carter. The Office Action asserts that "it would have been obvious to one of ordinary skill in the art . . . to modify the means of Alt to include the use of electrode switch circuitry as per the teachings of Carter et al".

However, so modified, Alt remains an implantable device having electrodes entirely within, not *on* a body, nor in particular, on an *external surface* of the body. As discussed above regarding the asserted 35 U.S.C. §102(e) rejection, Alt fails to disclose at least the limitations in applicants' independent claim 12, from which Claims 18-21 depend, and the distinct limitation(s) of which Claims 18-21 include (e.g., at least "multiple electrodes configured for . . . placement on the body").

For at least these reasons, as well as the reasons discussed above regarding the asserted 35 U.S.C. §102(e) rejection over Alt alone, applicants respectfully submit that the combined references fail to disclose at least the limitations of applicants' claim 3. Therefore, applicants respectfully submit that claim 3 is allowable over the references, either alone or when combined, and request withdrawal of the 35 U.S.C. § 103(a) rejection from claim 3.

CONCLUSION

Accordingly, applicant requests entry of the indicated amendments, reconsideration of the application on the merits, and allowance of the claims. The Examiner is encouraged to telephone the undersigned at (503) 226-1191 if it appears that an interview would be helpful in advancing the case.



Respectfully submitted,

Patrick D. Boyd
Patrick D. Boyd
Reg. No. 54,671
Ater Wynne LLP
222 SW Columbia, Suite 1800
Portland, Oregon 97201

Customer No. 35940